UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PRETRIAL ORDER # 66

(Agreed Order and Stipulation Regarding Hernia Mesh Documents)

Plaintiffs and Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson ("J&J") (collectively, "Defendants") have advised the court that they desire to enter into a stipulation concerning the production of hernia mesh documents for the Prolene, Prolene Soft, Ultrapro, Proceed and Vypro hernia mesh products. The stipulation also concerns the production of documents for additional hernia mesh products that contain the materials in the aforementioned products ("the Hernia Products."). The parties stipulate and agree as follows:

1. Ethicon will produce non-privileged documents for the Hernia Products responsive to the July 25, 2012 document requests served by Plaintiffs in this action (and will withdraw its "Specific Objection No. 1" to those document requests), as described more fully below, except as follows: By agreement of the parties, Ethicon is not required to produce documents for request numbers 1, 2, 8, 9, 10, 79, 84-106, 108-110, 112, 113, 115, and 118-124. Additionally, Ethicon is not required to produce sales and marketing documents in response to request numbers 3 and 4.

2. To respond to Plaintiffs' document requests, Ethicon will produce non-privileged responsive documents from general sources, central sources (e.g. SharePoints, groupshares) and custodians that it has a reasonable and good faith belief will yield documents responsive to Plaintiffs' requests.

3. The list of general sources from which responsive documents will be produced is attached hereto as Appendix 1. Plaintiffs may make reasonable requests that additional sources be added to Appendix 1. To the extent that there is a disagreement, the parties will meet and confer in an attempt to resolve the issue prior to seeking Court intervention.

4. This list of custodians from whom responsive documents will be produced is attached hereto as Appendix 2. Plaintiffs may make reasonable requests that additional custodians be added to Appendix 2. To the extent that there is a disagreement, the parties will meet and confer in an attempt to resolve the issue prior to seeking Court intervention.

5. Where appropriate, the data collected from custodians and central sources will be filtered by search terms attached hereto as Appendix 3. Plaintiffs may make reasonable requests to modify or add to the search terms. To the extent that there is a disagreement, the parties will meet and confer in an attempt to resolve the issue prior to seeking Court intervention.

6. Because Ethicon is still in the early stages in the hernia mesh litigation of identifying and collecting documents from the various hernia mesh central sources and custodians, many uncertainties remain concerning the volume, scope and location of responsive documents. Furthermore, the parties acknowledge that Plaintiffs' requests

seek many categories of documents for several of the Hernia Products, some of which have been marketed for many years, and that the custodians and central sources may be different from the pelvic mesh products in a number of instances. At any time, Plaintiffs may make reasonable requests for specific documents or categories of documents, or other tangible items, that are within the document requests, and Ethicon will make best efforts to accommodate those specific requests notwithstanding the production schedule set forth below. Although it is Ethicon's goal to accommodate Plaintiffs' requests as much as reasonably possible, the Parties agree to meet and confer about specific document requests, sources or custodians if it becomes apparent during the collection process that the cost or burden of the collection outweighs the relevancy of the data.

7. The parties will also work in good faith concerning the timing of the productions. Because of the sheer volume, productions will occur in a rolling fashion. In an effort to prioritize the production of certain categories of documents identified by Plaintiffs from among the materials described above, Ethicon will make reasonable efforts to produce documents pursuant to the following schedule. Should any of the time frames set forth below become unworkable, Ethicon will timely notify Plaintiffs and meet and confer to arrive at a mutually agreeable alternative time period.

8. Within 10 days of the date of this Order, Ethicon will make reasonable searches, as defined below, of documents that have already been produced to Plaintiffs to identify the following:

(a) Documents that reflect or refer to preclinical and animal study reports for the Hernia Products;

(b) Documents that reflect or refer to bench testing reports for the Hernia Products;

(c) Documents (including any attached media) that refer to Drs. Klosterhalfen, Klinge, and Heniford concerning the Hernia Products;

(d) Documents that reference heavyweight small pore design and light weight large pore design for the Hernia Products;

(e) Documents that reflect hernia mesh project meeting minutes for the Hernia Products.

9. Within 30 days of the date of the entry of this Order, Ethicon will make reasonable searches, as defined below, of documents that have been collected to date from the custodians identified in Appendix 2 and produce documents responsive to (a)-(e) in paragraph 8 above. The criteria to be used in connection with the searches described in paragraphs 8 and 9 are as follows:

(a) (hernia AND (animal* w/3 (preclinical OR stud*)) w/5 report*)

(b) (hernia AND ((bench w/3 test*) w/5 report*));

(c) (hernia AND (klosterhalfen OR "bernd.klosterhalfen@web.de" OR klinge OR "klinge@hia.rwth-aachen.de" OR "uklinge@ukaachen.de" OR (todd w/3 heniford) OR "todd.heniford@carolinashealthcare.org"));

(d) (hernia AND ((heavy* OR small*) w/3 pore*) OR ((light* OR large*) w/3 pore*));

(e) (hernia AND (meeting* w/3 minute*)).

Plaintiffs may make reasonable requests to modify or add to the search string, although such requests will impact the timing of the production of these materials. To the extent that there is a disagreement, the parties will meet and confer in an attempt to resolve the issue prior to seeking Court intervention.

10. Within 30 days of this order, Ethicon will make best efforts to identify testing conducted with respect to the Hernia Products and the types of documents that would be reasonably available for production.

11. Following Plaintiffs' inspection of the materials provided in the previous paragraphs, Plaintiffs may make reasonable requests for the production of data and other documents pertaining to those studies. To the extent such materials are reasonably available and the production of such materials does not impose undue burden, Ethicon will make best efforts to produce such materials within 45 days of plaintiffs' requests. To the extent the parties disagree as to the scope of such additional production, the parties shall meet and confer in an attempt to resolve the issue prior to seeking Court intervention.

12. Within 30 days of the date of this Order, Ethicon will produce the final Instructions for Use for Prolene, Prolene Soft, Ultrapro, Vypro and Proceed.

13. Also within 30 days of the date of this Order, Ethicon will produce the 510(k) premarket notifications and Design History Files for Prolene, Prolene Soft, Ultrapro, Vypro and Proceed.

14. Within 45 days of the date of this Order, Ethicon will produce the following documents to the extent that they are reasonably available in a centralized location:

(a) Device Design Safety Assessments (DDSA's) and Failure Mode Effect Analyses (FMEA's) for Prolene, Prolene Soft, Ultrapro, Vypro and Proceed;

(b) FDA correspondence regarding Prolene, Prolene Soft, Ultrapro, Vypro and Proceed , including FDA 483 Warning Letters;

(c) The remaining documents for Prolene, Prolene Soft, Ultrapro, Vypro and Proceed that are contained in the general sources attached hereto as Appendix 1.

15. Within 90 days of the date of this Order, Defendants agree to produce the following information:

(a) Backup data including tissue slides and full study materials for the Hernia Products, except that the parties shall meet and confer to determine which slides and materials are relevant and/or not cost-prohibitive to produce;

(b) All internal documents or internal communications related to Ethicon's decision to redesign the Hernia Products to move from a heavyweight small pore design to a lighter-weight, larger pore hernia mesh from the custodians listed on Appendix 2, as may be modified by the parties, as well as any reasonably identifiable central sources.

(c) Copies of all patent submissions and final patent approvals for the Hernia Products.

(d) All CE Mark technical files for the Hernia Products that are reasonably available and do not impose undue burden to collect and produce.

(e) All project meeting minutes for the Hernia Products from the custodians in Appendix 2, as may be modified by agreement of the parties, as well as any reasonably identifiable central sources.

16. Additionally, Ethicon agrees to produce in the current litigation the documents produced in the ongoing hernia mesh litigation (except with respect to plaintiff-specific materials) as they are produced in the hernia mesh litigation.

17. The documents produced pursuant to this Agreed Order and Stipulation will be governed by the provisions of the ESI Protocol (PTO No. 13) and the Stipulated Protective Order (PTO No. 11).

18. Absent a showing of good cause, by the end of 6 months of the Parties' agreement to this stipulation, Defendants agree to make best efforts to produce the balance of the documents from the general sources and custodians identified in Appendix 1 and Appendix 2 as may be modified by the parties.

19. Defendants shall certify that Defendants have conducted reasonable and diligent searches for the materials agreed to be provided in connection with this Order and that responsive documents have been produced.

20. To the extent any of these documents bear on the opinions of the Plaintiffs' experts, the Parties agree that those experts shall be permitted to seasonably supplement their reports.

The court hereby accepts the stipulation of the parties. It is so **ORDERED.**

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-22633. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at **http://www.wvsd.uscourts.gov**.

ENTERED: September 6, 2013.

Cheryl A. Eifert
United States Magistrate Judge

APPROVED:

/s/Bryan F. Aylstock
/s/Tom P. Cartmell
/s/ D. Renee Baggett

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